4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0021]

# Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Generally Recognized as Safe: Notification Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0495. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Substances Generally Recognized as Safe: Notification Procedure--21 CFR 170.36 and 570.36

(OMB Control Number 0910-0342)--Extension

Section 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348) establishes a premarket approval requirement for "food additives"; section 201(s) of the FD&C Act (21 U.S.C. 321(s)) provides an exclusion to the definition of "food additive" and thus from the premarket approval requirement, for uses of substances that are generally recognized as safe (GRAS) by qualified experts. In the Federal Register of April 17, 1997 (62 FR 18938) (the 1997 proposed rule), we published a proposed rule that would establish a voluntary procedure whereby manufacturers would notify us about a view of a particular use (or uses) of a substance that is not subject to the statutory premarket approval requirements based on a determination that such use is GRAS. Under an interim policy announced in the proposed rule, we invited manufacturers to submit notices of their independent determinations for review under the framework of the proposed rule during the period between issuance of the proposal and any final rule based on the proposal. The proposed regulations (proposed 21 CFR 170.36 and 21 CFR 570.36) provide a standard format for the voluntary submission of a notice.

To assist respondents in submissions to our Center for Food Safety and Applied Nutrition (CFSAN), we developed Form FDA 3667 entitled "Generally Recognized as Safe (GRAS) Notice." The form, and elements prepared as attachments to the form, may be submitted in electronic format via the Electronic Submission Gateway (ESG), or may be submitted in paper format, or as electronic files on physical media with paper signature page. While we do not expect Form FDA 3667 to reduce reporting time for respondents, use of the form helps to

expedite our review of the information being submitted. For submissions to our Center for Veterinary Medicine (CVM), respondents may continue to send GRAS notices in letter format to the Agency, as instructed in our Federal Register notice of June 4, 2010 (75 FR 31800).

Presently, we have committed to issuing a final rule regarding "Substances Generally Recognized as Safe" in 2016, as part of a settlement agreement with the Center for Food Safety, which filed a lawsuit in 2014 seeking to vacate our 1997 proposed rule.

Description of Respondents: The respondents to this collection of information are manufacturers of substances used in food and feed.

In the Federal Register of September 17, 2015 (80 FR 55857), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received a number of comments in support of the information collection generally. We also received one comment suggesting that the names, credentials, and affiliations of "qualified experts" associated with GRAS determinations be included on the form. We received a second comment suggesting that information submitted by manufacturers be reviewed by independent scientists. We appreciate this input. As discussed previously, rulemaking is underway that will necessitate a revision to the information collection provisions associated with our GRAS program and we continue to consider all comments.

We estimate the burden of this collection of information as follows:

Table 1--Estimated Annual Reporting Burden[1]

| 21 CFR Section | Form No. [2] | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|---|
| 170.36 (CFSAN) | 3667[3] | 40 | 1 | 40 | 150 | 6,000 |
| 570.36 (CVM) | N/A | 20 | 1 | 20 | 150 | 3,000 |
| Total | | | | | | 9,000 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Only CFSAN uses Form FDA 3667.
[3] Form FDA 3667 may be submitted electronically via the ESG.

Table 2--Estimated Annual Recordkeeping Burden[1]

| 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|---|---|---|---|---|---|
| 170.36(c)(v) (CFSAN) | 40 | 1 | 40 | 15 | 600 |
| 570.36(c)(v) (CVM) | 20 | 1 | 20 | 15 | 300 |
| Total | | | | | 900 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

For purposes of this extension request, we are retaining our 2012 estimates. The PRA analysis for the GRAS final rule will take into account any changes to the GRAS notification procedure as set forth in the final rule and we will revise the collection accordingly.

Dated: February 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-03330 Filed: 2/17/2016 8:45 am; Publication Date: 2/18/2016]